K051322

AUG 5 - 2005

smiths

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Summary of Safety and Effectiveness

Submitter:	**Smiths Medical International Ltd.**
Address:	**Bramingham Business Park, Enterprise Way, Luton, Bedfordshire, LU2 OAH United Kingdom.**
Telephone:	**(+44) (0) 1582 430000**
Contact:	**Senior UK Regulatory Manager**
Prepared:	**29th February 2005**
Proprietary Name:	**Pneupac VR1 Standard and Pneupac VR1 Responder**
Common/ Classification Name:	**Gas powered Emergency and Transport Ventilator**
Regulatory Class:	**II (two)**
Product Code:	**BTL**
Classification Number:	**21 CFR 868.5925**
Predicate Device:	**Genesis II A/C model Ventilator, Emergency, Powered (K932170).**

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New Device Description:

Pneupac VR1 Standard and VR1 Responder is intended for emergency resuscitation by medical personnel, paramedics and ambulance technicians inside and outside hospital and for ventilation by medical personnel inside and outside hospital in emergency situations and for intra- and inter-hospital transport.

The Pneupac VR1 range comprises two variants – Pneupac VR1 (standard model) and Pneupac VR1 Responder (standard model without spontaneous breathing system).

The Pneupac VR1 Standard and VR1 Responder allow two modes of ventilation, automatic and manual. In automatic mode the device cycles in accordance with the setting of the single tidal volume/frequency control that changes the tidal volume and frequency dependently whilst maintaining a constant I:E ratio of 1:2. In manual mode, preset breaths, singly or in a controlled breathing pattern may be selected by use of an omni-directional lever or push button. The tidal volume and rate possible are limited by the position of the single tidal volume/frequency control.

The Pneupac VR1 Standard and VR1 Responder use the same technology as existing legally marketed devices and depends solely on the pressure of the supply gas for its operation.

The Pneupac VR1 Standard and VR1 Responder incorporate a pneumatic high-pressure audible alarm which dumps excess patient pressure according to the in-built relief pressure (40 cmH_2O standard, 60cmH_2O optional) which operates in an identical manner to the predicate devices.

The Pneupac VR1 Standard and VR1 Responder consists of a hand-held control module connected to the patient at its outlet via a mask, endotracheal tube or laryngeal mask airway and is used with various patient circuits and accessories comprising the following items;

- User replaceable patient valve
- Oxygen input gas hose assemblies
- Breathing filter
- Biological breathing filter kit (optional for contaminated atmospheres)
- Masks, airways and airway adjuncts
- Manual suction
- Oxygen therapy kits
- Oxygen cylinders and regulators
- Carrying bag

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New Device Description (ctd.):

- Breathing circuits
- PEEP accessories

The specification for the recommended, optional biological breathing filter are as follows;

- Filter efficiency at least 99.99% efficient against a 0.3micron mass median aerodynamic diameter aerosol challenge at 32 l/min.
- Airflow resistance at 32 l/min. is 10-17 mm H2O
- Connector size 40mm DIN NATO compatible threads

The mass of Pneupac VR1 Standard and VR1 Responder resuscitators is;
Pneupac VR1 0.880lb, 0.400kg
Pneupac VR1 Responder 0.825lb, 0.375kg

The Pneupac VR1 Standard and VR1 Responder standard control module has the following features;

- Interdependent and continuous control of tidal volume and frequency from 150ml/25bpm to 1050ml/10bpm using a single tidal volume/frequency control
- Demand breathing system (*not featured on the VR1 Responder model*)
- Spontaneous breathing under power failure
- Audible pressure relief alarm
- Integrated, user replaceable patient valve
- Automatic or Manual mode selector
- Manual mode push button and omni-directional lever

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Intended Use:

The Pneupac VR1 range are hand held portable, time cycled, gas powered, flow generator ventilatory resuscitators that are suitable for emergency and transport use and will operate safely in an MRI environment up to 3 Tesla.
They are designed for use by qualified medical caregivers, paramedics and other trained personnel for the following conditions:

- VR1 Standard - Ventilatory resuscitator intended for use on adults and children above a bodyweight of 22 lb (10 kg) with either respiratory distress/ insufficency or no respiratory function.

- VR1 Responder - Basic ventilatory resuscitator intended for use on adults and children above a bodyweight of 22 lb (10 kg) with no respiratory function.

Performance data:

Testing was performed to ensure that the Pneupac VR1 Standard and VR1 Responder was safe and would perform within the environment(s) for which they are to be marketed.
Safety testing was conducted in accordance with;
ASTM F 920-93 'Minimum Performance and Safety Requirements for Resuscitators Intended for Use With Humans',
RTCA DO160D section 4.6.2 10,000ft to 20,000ft,
RTCA DO160D section 8 profile C, and
RTCA DO160D section 12.
The resuscitator passed all of these tests and met all requirements of the standards.

Environmental testing was performed in accordance with;

- Operating and extended temperature/humidity, ETR784 to ASTM F920-93 section 8.2 and Smiths input requirements.
- Storage temperature/humidity, ETR745 to ASTM F920-93 section 8.1
- Vibration, ETR754 to MIL-STD 810F section 514.4 and RTCA DO160D section 8 profile C
- Altitude, ETR755 to MIL-STD 810F section 500.4, RTCA DO160D section 4.6.2 10,000ft to 20,000ft and Smiths input requirements
- MRI, ETR752 to 3 Tesla
- IP rating, ETR750 to IEC 529 rating IP5x, IPx5, Ipx6 and Ipx7

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Performance data (ctd):

- Driving sand & dust, ETR750 Smiths input requirements
- Immersion in water, ETR750 to ASTM F920-93 section 5.5
- Mechanical shock (drop), ETR758 to ASTM F920-93 section 5.4.1
- Rigidity, ETR757
- Cleaning & sterilisation, ETR743

The results demonstrated that the Pneupac VR1 Standard and VR1 Responder complied with the guidelines and standards and that they performed within their specifications and functional requirements.

A comparison table was constructed to show the similarity in parformance between Pneupac VR1 Standard and VR1 Responder and the predicate device; O-Two Medical Technologies Inc. Genesis II (K932170)

Based on these results, it is our determination that the device model(s) are safe, effective and perform as well as the legally marketed predicate device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully,
Colin Walters
Colin Walters
Senior UK Regulatory Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 5 - 2005

Smiths Medical International, Limited
C/O Mr. Donald Alexander
VP Regulatory Affairs
Smiths Medical P.M., Incorporated
N7 W22025 Johnson Drive
Waukesha, Wisconsin 53186

Re: K051322
Trade/Device Name: Pneupac VR1 Standard and Pneupac VR1 Responder
Regulation Number: 21 CFR 868.5925
Regulation Name: Powdered emergency ventilator
Regulatory Class: II
Product Code: BTL
Dated: May 17, 2005
Received: May 20, 2005

Dear Mr. Alexander:

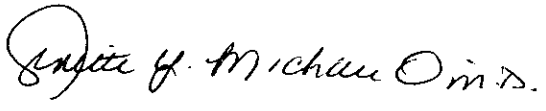
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051322

Device Name: Pneupac VR1 Standard and Pneupac VR1 Responder

Indications For Use: The Pneupac VR1 range are hand held portable, time cycled, gas powered, flow generator ventilatory resuscitators that are suitable for emergency and transport use and will operate safely in an MRI environment up to 3 Tesla.
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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051322